FORM PTO-1390 U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE (REV. 1094) TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US) CONCERNING A FILING UNDER 35 U.S.C. 371		ATTORNEY'S DOCKET NUMBER U0139/7000 09/980971 U.S. APPLICATION NO. (If known, see 37 CFR 1.5) JC18 Rec'd PCT/PTO 26 OCT 2001
INTERNATIONAL APPLICATION NO. PCT/GB00/01725	INTERNATIONAL FILING DATE 05 May 2000 (05.05.00)	PRIORITY DATE CLAIMED 06 May 1999 (06.05.99)
TITLE OF INVENTION CARDIAC DEFIBRILLATION		
APPLICANT(S) FOR DO/EO/US ANDERSON, John McCune, EVANS, Nocl		

Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:

1. ☒ This is a **FIRST** submission of items concerning a filing under 35 U.S.C. 371.
2. ☐ This is a **SECOND** or **SUBSEQUENT** submission of items concerning a filing under 35 U.S.C 371.
3. ☒ This express request to begin national procedures (35 U.S C 371(f) at any time rather than delay examination until the expiration of the applicable time limit set in 35 U S.C. 371(b) and PCT Articles 22 and 39(1).
4. ☒ A proper Demand for International Preliminary Examination was made by the 19th month from the earliest claimed priority date.

5. ☒ A copy of the International Application as filed (35 U.S.C. 371(c)(2)).
   a. ☒ is transmitted herewith (required only if not transmitted by the International Bureau).
   b. ☐ has been transmitted by the International Bureau.
   c. ☐ is not required, as the application was filed in the United States Receiving Office (RO/US).

6. ☐ A translation of the International Application into English (35 U.S.C. 371(c)(2)).

7. ☒ Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3)).
   a. ☐ are transmitted herewith (required only if not transmitted by the International Bureau).
   b. ☐ have been transmitted by the International Bureau.
   c. ☐ have not been made; however, the time limit for making such amendments has NOT expired.
   d. ☒ have not been made and will not be made.

8. ☐ A translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).

9. ☐ An oath or declaration of the inventor(s) (35 U.S.C. 371©(4)).

10. ☐ A translation of the annexes to the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(C)(5)).

Items 11. To 16. Below concern document(s) or information included:

11. ☐ An Information Disclosure Statement under 37 CFR 1.97 and 1.98 with references.

12. ☐ An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.

13. ☐ A FIRST preliminary amendment.

14. ☐ A SECOND or SUBSEQUENT preliminary amendment.

15. ☐ A substitute specification.

16. ☐ A change of power of attorney and/or address letter.

17. ☐ A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 35 U.S.C.1.821-1.825.

18. ☐ A second copy of the published international application under 35 U.S.C. 154(d)(4).

19. ☐ A second copy of the English language translation of the international application under 35 U.S.C. 154(d)(4).

20. ☒ Other items or information:
    Copy of page 1 of PCT Published Application
    Copy of International Search Report as Published
    Copy of International Preliminary Examination Report w/Annexes

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U.S. APPLICATION NO (if known, see 37 CFR 1.5)	INTERNATIONAL APPLICATION	ATTORNEY'S DOCKET NUMBER
09798097	PCT/GB00/01725	U0139/7001

21. ☒ The following fees are submitted:	CALCULATIONS PTO USE ONLY
BASIC NATIONAL FEE (37 CFR 1.492(a)(1)-(5)):	
Neither international preliminary examination fee (37 CFR 1.482) nor international search fee (37 CFR 1.445(a)(2)) paid to USPTO and International Search Report not prepared by the EPO or JPO $1000.00	
International preliminary examination fee (37 CFR 1.482) not paid to USPTO but International Search Report prepared by the EPO or JPO $860.00	
International preliminary examination fee (37 CFR 1.482) not paid to USPTO but but international search fee paid to USPTO (37 CFR 1.445(a)(2)) paid to USPTO $710.00	
International preliminary examination fee paid to USPTO (37 CFR 1.482) But all claims did not satisfy provisions of PCT Article 33(1)-(4) $690.00	
International preliminary examination fee paid to USPTO (37 CFR 1.482) and all claims satisfied provisions of PCT Article 33(1)-(4) $100.00	
ENTER APPROPRIATE BASIC FEE AMOUNT =	$ 860 00
Surcharge of $130.00 for furnishing the oath or declaration later than ☐ 20 X 30 Months from the earliest claimed priority date (37 CFR 1.492(e)).	$ 130 00

CLAIMS	NUMBER FILED	NUMBER EXTRA	RATE		
Total Claims	11- 20 =	0	X $18.00	$ 0.00	
Independent Claims	2- 3 =	0	X $80.00	$ 0.00	
MULTIPLE DEPENDENT CLAIM(S) (if applicable)			+$270.00	$ 270 00	
TOTAL OF ABOVE CALCULATIONS			=	$ 1260.00	
☒ Applicant claims small entity status. See 37 CFR 1.27. The fees indicated above Are reduced by ½.				$ 630.00	
SUBTOTAL			=	$ 630.00	
Processing fee of $130.00 for furnishing the English translation later than ☐ 20 ☐30 Months from the earliest claimed priority date (37 CFR 1.492(f)).				$	
TOTAL NATIONAL FEE			=	$ 630.00	
Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate coversheet (37 CFR 3.28, 3.31). $40.00 per property			+	$	
TOTAL FEES ENCLOSED			=	$ 630.00	
				Amount to be: refunded	$
				charged	$

a. ☐ A check in the amount of $_____ to cover the above fees is enclosed.

b. ☒ Please charge by Deposit Account No. 23/2825 In the amount of $ 630.00 To cover the above fees. A duplicate copy of this sheet is enclosed.

c. ☒ The commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 23/2825. A duplicate of this sheet is enclosed.

d. ☐ Fees are to be charged to a credit card. WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

NOTE: Where an appropriate time limit under 37 CFR 1.494 or 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b) must be filed and granted to restore the application to pending status.

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34,654
REGISTRATION NO

Cardiac Defibrillation

This invention relates to cardiac defibrillation, and in particular (but not exclusively) to an apparatus for delivering an electrical defibrillating signal to a human heart in the state of atrial fibrillation (AF), using transdermal energy transfer to a passive implanted device.

Atrial fibrillation is a common heart arrhythmia that increases in prevalence with age, with typically 10% of people over the age of 70 experiencing an incident. The process of cardioversion of AF to normal sinus rhythm (SR) has traditionally been attempted by pharmacological measures or transthoracic direct current shock. The former has been limited by variable cardioversion rates and the risk of side effects, in particular proarrhythmia. The latter requires sedation or anaesthesia and high energy shocks, and there is a high recurrence rate. For these reasons, there has been interest in catheter-based transvenous atrial defibrillation and its potential use in an implantable atrial defibrillator. However, atrial implantable defibrillators are complex devices requiring on-board pattern recognition with complex recording and follow-

up procedures. The need for electrical charging circuitry using active devices adds to the complexity and weight of the implant.

The present invention provides an apparatus for cardiac defibrillation which comprises an external circuit and an implantable circuit; the external circuit including an induction transmitting coil and signal generating means for applying radio frequency pulses of predetermined shape to the transmitting coil; the implantable circuit including an induction receiving coil for receiving pulses when the two coils are in proximity, and a rectification circuit having an input connected to the receiving coil and an output driving electrodes implantable in the heart.

In a preferred form of the invention, for use in atrial defibrillation, the power transmitted per pulse is less than about 5J and the radio frequency is in the range 3-30 MHz, typically about 7MHz.

Most preferably, the implantable circuit contains only passive components.

From another aspect the invention provides a method of cardiac (preferably atrial) defibrillation which comprises transmitting pulses of controlled shape and energy transdermally by high frequency magnetic induction to a substantially passive implanted circuit which includes electrodes implanted in the heart.

It is known to transfer energy transdermally by induction, but only for purposes of recharging batteries in implanted devices such as pacemakers or continuously powering implanted devices such as pumps. It has not hitherto been proposed to use such

techniques to transfer controlled waveforms for high-energy physiological stimulation.

An embodiment of the invention will now be described, by way of example, with reference to the accompanying drawings, in which:

Figure 1 shows the elements required for controlled, transdermal energy delivery to a cardiac load;
Figure 2 illustrates the circuitry required external to the body;
Figure 3 represents the body-internal circuitry; and
Figure 4 illustrates waveforms in the apparatus.

In the apparatus (Figure 1), an appropriately synchronised trigger pulse is firstly generated, based on the subject's electrocardiogram (ecg). This pulse, after shaping in a pulse generation and shaping circuit 12 to a waveform 1 suitable for AF conversion, is used to amplitude modulate a radio frequency (RF) carrier generator 2 at a power level consistent with the transmission of 1-5 J of energy to the internal load, itself nominally 50 Ω resistive. The transmission path takes the form of a pair of coaxially-aligned transmit 3 and receive 4 inductors constructed in the form of an RF transformer. The diameters of the coils 3 and 4 are set so as to optimise energy transfer at a physical spacing not less than the thickness of the thoracic wall 13. Both inductors are wound with enamelled copper wire. The transmitting coil 3 is mounted on an insulated paddle to facilitate adjustment in its placement on the subject's body. The implanted circuitry is mounted on a printed circuit board and consists of the receiving coil 4 connected to impedance matching, rectification and wave-shaping components 5. The final defibrillating signal is connected to the

heart (indicated as an electrical load 6) by catheters 7, one placed in the lateral right atrium (RA) and the other in the distal great cardiac vein via the coronary sinus. Alternatively, any conventional atrial defibrillation delivery system may be used.

In one example, the coils 3 and 4 are designed to give optimum inductive coupling at a centre-to-centre spacing of 20mm. Given a maximum diameter, for practicability, of the receiving coil 4 of 35mm, the transmitting coil 3 has a diameter of 53mm. Both inductors are wound with 1.5mm enamelled copper wire. The transmitting coil 3 is arranged as a solenoidal coil, spaced at one turn. The receiving coil 4 is pile-wound to conserve space in the final implant.

Both inductors in the apparatus are tuned to resonance at the selected operating frequency of the system, typically in the range 3-30 MHz. As seen in Fig. 2, the transmitter uses series tuning by capacitor 9. Fig. 2 also shows a 50 ohm feed 15 from the generator 2, giving an operational loaded Q of approximately 5. Referring to Fig. 3, the receiving coil is parallel tuned, with capacitive matching to the load 6 by means of capacitors C1 and C2. A radio-frequency choke 11 provides a DC path for rectifier current. Rectification and shaping is effected in circuit 16.

Optionally, as shown in Figure 1 a telemetry link 8 may be incorporated to provide ecg monitoring and feedback-derived, automatic tuning of the energy delivery system. Such a link may also be powered from energy delivered transdermally, by using a low-power transfer to power up the telemetry link, or to charge an on-board battery. Alternatively, the ecg could be transmitted via the induction coils using a suspended

carrier technique.

As is also indicated in Figure 1, the external circuitry may include a remote communication link 14, which may be via telephone communication (landline or GSM) or via a radio link. This would, for example, enable the patient's ecg to be transmitted to a hospital for monitoring and for inspection by a physician. Defibrillation could be activated remotely, and spoken instructions could be conveyed to the patient.

Atrial defibrillation currently requires a pulse energy of about 3 to 4J. By using a tuned inductive coupling as described, typically at a frequency about 7 MHz, these energy levels can be transmitted transdermally while maintaining control of pulse shape and timing. It is contemplated that by refining the pulse shape, duration and timing required to achieve defibrillation the energy necessary could be reduced to 1J or less, which would be painless to the patient and remove any need for sedation.

The pulse form 1 shown in Figure 1 is a biphasic pulse, which is the form we currently prefer. However, other pulse forms and hence RF envelope shapes may also be used, such as monophasic and multiple. Fig. 4 illustrates waveforms of the apparatus in more detail. Fig. 4a is a typical trigger input from an ecg. Fig. 4b shows a typical RF output envelope to the coil 3 as a single pulse. Fig. 4c shows an alternative RF output envelope as a burst of two or more pulses. All pulses can be controlled in width, and the inter-pulse gap of Fig. 4c is programmable. Each RF pulse, after transmission and rectification, results in either a monophasic or a biphasic (baseband) voltage waveform

suitable for driving the cardiac load. Fig. 4d shows a monophasic pulse 17 and a biphasic pulse 18 which can be produced from the single pulse of Fig. 4a.

Although described above with particular reference to atrial defibrillation, the invention could find use in ventricular defibrillation. Here, though, the required energy levels are much higher (typically about 15J).

It will be appreciated that one of the benefits of the embodiment described is that the implanted hardware is entirely passive and does not require any implanted power source. However, the invention does not exclude the possibility of some active components being implanted, with a reduced requirement for an internal source of power.

CLAIMS

1. An apparatus for cardiac defibrillation which comprises an external circuit and an implantable circuit; the external circuit including an induction transmitting coil and signal generating means for applying radio frequency pulses of predetermined shape to the transmitting coil; the implantable circuit including an induction receiving coil for receiving pulses when the two coils are in proximity, and a rectification circuit having an input connected to the receiving coil and an output driving electrodes implantable in the heart.

2. An apparatus according to claim 1, for use in atrial defibrillation, in which the power transmitted per pulse is less than about 5J and the radio frequency is in the range 3-30 MHz, preferably about 7MHz.

3. An apparatus according to claim 1 or claim 2, in which the signal generating means comprises a radio frequency generator switched or gated under the control of a pulse generation and shaping means which in turn is responsive to an ecg synchronisation signal.

4. An apparatus according to claim 3, in which the ecg synchronisation signal is provided via a telemetry transmitter implanted in the patient.

5. An apparatus according to any preceding claim, in which the external circuit further includes a telephony link by which the ecg may be transmitted to, and/or the apparatus controlled from, a remote location.

6. An apparatus according to any preceding claim, in which the external and implantable circuits include

impedance matching components to achieve a high degree of tuning.

7. An apparatus according to claim 6, in which the inductive coupling is tuned to resonance.

8. An apparatus according to claim 8, in which the inductive coupling is tuned to resonance by use of series resonance in the external circuit and parallel resonance in the implantable circuit.

9. An apparatus according to any preceding claim, in which the implantable circuit contains only passive components.

10. A method of cardiac defibrillation which comprises transmitting pulses of controlled shape and energy transdermally by high frequency magnetic induction to a substantially passive implanted circuit which includes electrodes implanted in the heart.

11. The method of claim 10, in which the electrodes are implanted to provide atrial defibrillation.

PCT

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Published

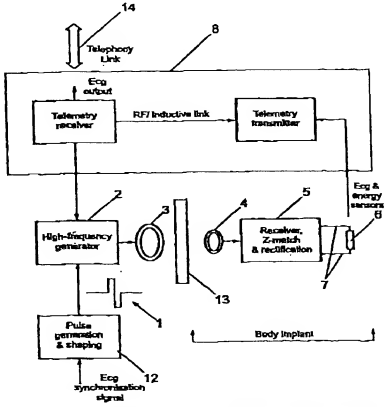
With international search report.

Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.

(54) Title: CARDIAC DEFIBRILLATION

(57) Abstract

A defibrillator connected by catheters (7) to the heart (6) has an external circuit (2, 12) connected to a passive implanted circuit (5) by transdermal induction via coils (3, 4). For atrial defibrillation, pulses of 3–4J can be transmitted at about 7MHz without damage, using an implated coil (4) of 20mm diameter.



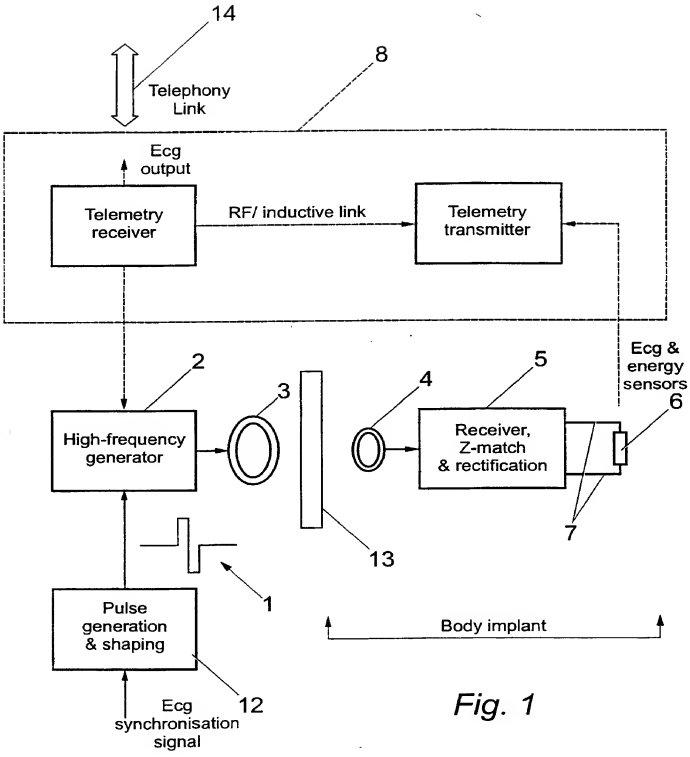

14
Telephony Link
8
Ecg output
Telemetry receiver
RF/ inductive link
Telemetry transmitter
Ecg & energy sensors
2
3
4
5
6
High-frequency generator
Receiver, Z-match & rectification
7
13
1
Pulse generation & shaping
Body implant
Ecg synchronisation signal
12

Fig. 1

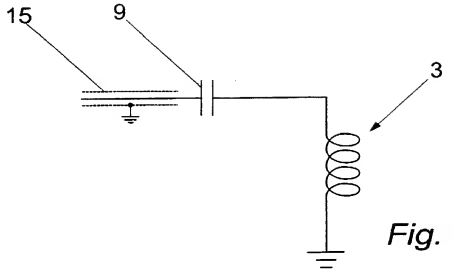


Fig. 2

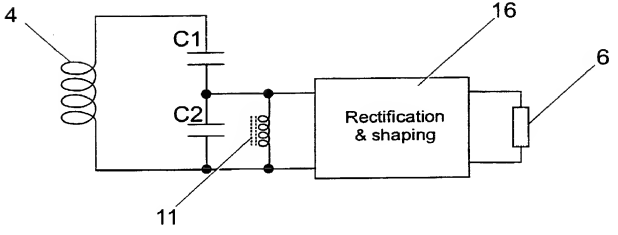


Fig. 3

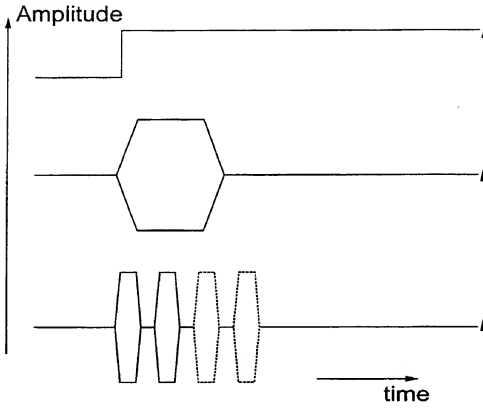


Fig. 4a

Fig. 4b

Fig. 4c

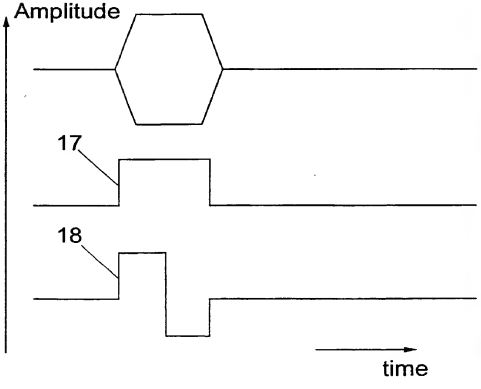


Fig. 4d

Attorney Docket No. U0139/7001

DECLARATION FOR PATENT APPLICATION

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name.

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled

CARDIAC DEFIBRILLATION

the specification of which is attached hereto unless the following is checked:

[x] was filed on October 26, 2001, as U.S. Application No. 09/980,971, bearing attorney docket No. U0139/7001, and was amended on (if applicable).

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information which is material to the examination of this application in accordance with Title 37, Code of Federal Regulations, §1.56.

I hereby claim foreign priority benefits under Title 35, United States Code, §119(a)-(d) or §365(b) of any foreign application(s) for patent or inventor's certificate, or section 365(a) of any PCT International application designating at least one country other than the United States listed below and have also identified below any foreign application for patent or inventor's certificate or PCT International application having a filing date before that of the application on which priority is claimed:

Prior Foreign PCT International Application(s)and any priority claims under 35 U.S.C. §§119 and 365(a),(b):

(Number)	(Country-if PCT, so indicate)	(DD/MM/YY Filed)	Priority Claimed YES	NO
PCT/GB00/01725	PCT	05/05/2000	[x]	[ ]
			[ ]	[ ]
			[ ]	[ ]

I hereby claim the benefit under Title 35, United States Code, §119(e) of any United States provisional application(s) listed below:

(Application Number)	(filing date)
(Application Number)	(filing date)

I hereby claim the benefit under Title 35, United States Code, §120 of any United States application(s), or §365(c) of any PCT International application(s) designating the United States of America listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States or PCT International application in the manner provided by the first paragraph of Title 35, United States Code, §112, I acknowledge the duty to disclose material information as defined in Title 37, Code of Federal Regulations, §1.56 which became available between the filing date of the prior application and the national or PCT International filing date of this application:

PCT/GB00/01725	05/05/00	Published
(Application No.)	(filing date)	(status-patented, pending, abandoned)

PCT International Applications designating the United States:

(PCT Appl. No.)	(U.S. Ser. No.)	(PCT filing date)	(status-patented,pending,abandoned)

I hereby appoint the following attorney(s) and/or agent(s) to prosecute this application and to transact all business in the Patent and Trademark Office connected therewith:

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I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

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